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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,199	08/09/2005	Jean-Paul Gilbert Ricol	80350-1350	5197

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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01/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,199	RICOL ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-12 and 15-19* is/are pending in the application.

4a) Of the above claim(s) *6-12,18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

References to paragraphs in non-patent literature refer to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Election/Restrictions

To summarize the election, applicants elected Group I with traverse.

Claims 6-12 and 18-19 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Note to Applicants

Upon further consideration of the specification and claims it appears that the text of on page 6 line 4 as well as claims 3 and 15 may have an error in the translation from the original French. The original text was "une nappe de structure" which was translated as "top layer", but "sheet" may be a translation more in accordance with the described invention. There is no discussion in the disclosure of multiple layers (e.g. top and bottom layer) within the textile support and the depiction of the invention in the figure also does not include a multilayered textile support. For the sake of application of prior art, the "top layer" is interpreted as a top portion of the textile structure such that textile structure that is non-woven, woven, knitted, or interlaced, will be interpreted to meet the limitations of claims 3 and 15.

NEW REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. (previously cited) in view of Noishiki (previously cited).

Orgill et al. teach a textile mesh with a freeze dried (lyophilisate) collagen-glycosaminoglycan blend (see page 16 lines 5-16). In addition, Orgill et al. teach hyaluronic acid as an envisioned glycosaminoglycan (see page 7 line31-page 8 line 3; instant claim 1). All textiles are either woven or non-woven; therefore the textile taught by Orgill et al. meet the limitations of instant claims 3 and 15. This reference does not explicitly teach the molecular weight of the hyaluronic acid.

Noishiki teach a prosthetic device with a bioabsorbable material (see abstract). In particular hyaluronic acid is taught as a known bioabsorbable material and its molecular weight is disclosed by Noishiki (see column 5 lines 66-67 and column 6 lines 19-20). This molecular weight is taught to range from about 10,000 to 2,000,000 Daltons (see column 6 lines 21-22; instant claim 2).

As a known option used in the same context, it would have been obvious to one of ordinary skill in the art at the time of the invention to select a hyaluronic acid between about 10,000 to 2,000,000 Daltons for the invention of Orgill et al. Additionally, routine experimentation within this range would have made the molecular weight range of instant claim 2 obvious to one of ordinary skill in the art. Therefore claims 1-3 and 15 are obvious over Orgill et al. in view of and Noishiki.

Claims 1-2, 4, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. in view of Noishiki as applied to claims 1-3 and 15 above, and further in view of Perciaccante et al. (US Patent No. 4,047,533).

Orgill et al. in view of Noishiki make obvious the limitations of claims 1 and 2. Orgill et al. also teaches particular textile materials that are envisioned in the composite and include the polyester polyglycolic acid, exemplifying the variety sold under the name Daxon® (see page 8 lines 29-31; instant claims 4 and 16). The modified reference does not explicitly teach that this polyester material is a single-strand or multi-strand material.

Perciaccante et al. teach that the polyglycolic acid suture material sold under the name Daxon® is a multi-filament strand (see column 3 lines 39-54; instant claims 4 and 16).

As one of a limited list of options, it would have been obvious to one of ordinary skill in the art at the time of the invention to select a multi-strand polyglycolic acid material for the structural biomaterial in the invention of Orgill et al. in view of Noishiki. Therefore claims 1-2, 4, and 16-17 are obvious over Orgill et al. in view of Noishiki and Perciaccante et al.

Response to Arguments

Applicants' arguments, filed October 26, 2009, have been fully considered but they are not deemed to be persuasive.

Regarding the rejections under 35 USC 103(a):

Orgill et al. in view of Noishiki - Applicants argue that Noishiki does not teach the molecular weight of hyaluronic acid that should be used in lyophilisate form. This assertion is not correct. Noishiki teach hyaluronic acid as an envisioned bioabsorbable substance whose molecular weight is between about 10,000 and 2,000,000 Daltons (see column 5 lines 67-68, column 6 lines 5 and 19-22). He goes on to teach the lyophilization of the taught bioabsorbable materials after application to a device structure (see column 7 lines 51-60). Therefore he does contemplate these molecular weights for lyophilized material on a medical device structure. Applicants argue that Noishiki limits the use of the bioabsorbable materials to one set of production processes, but there is no such explicit or implicit limitation. Noishiki teaches the lyophilization of the taught bioabsorbable materials during application to device structures and do not limit the envisioned materials that are suitable for this process. Applicants also argue that there is no reason to combine the references. Both Orgill et al. and Noishiki et al. teach glycosaminoglycans used to coat implantable medical device structures for the purpose of improving their biocompatibility (e.g. reduction in foreign body response). Thus there would have been good reason for one of ordinary skill in the art to combine their teachings.

Applicants' arguments against the remaining rejections reiterate the arguments presented against Orgill et al. in view of Noishiki. These arguments were addressed above and are similarly reiterated.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615